

04/01/98

Patent No. 20350
 TOWNSEND and TOWNSEND and CREW LLP
 Two Embarcadero Center, 8th Floor
 San Francisco, CA 94111-3834

PATENT APPLICATION
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 Washington, D. C. 20231

Atty. Docket No. 18661-000100

"Express Mail" Label No. EM035053233US

Date of Deposit April 1, 1998

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☒ patent application, ☐ continuation patent application,
☐ divisional patent application, or ☐ continuation-in-part
 patent application of

By John P. Borg
 John P. Borg

Inventor(s)/Applicant Identifier: MARY S. ROGONE AND AUSTIN J. WEBBER II

For: THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS

- ☐ This application claims priority from each of the following Application Nos./filing dates:
 _____; _____; _____, the disclosure(s) of which is
 (are) incorporated by reference.
☐ Please amend this application by adding the following before the first sentence: --This application is a ☐ continuation ☐ division of and
 claims the benefit of U.S. Application No. _____, filed _____, the disclosure of which is incorporated by reference.--

Enclosed are:

- ☒ 5 sheet(s) of ☐ formal ☒ informal drawing(s); 14 pages of specification including description, claims and abstract; ☒ title page.
☒ An assignment (and Recordation Transmittal) of the invention to SMALL BEGINNINGS
☐ A ☐ signed ☐ unsigned Declaration & Power of Attorney.
☒ A ☒ signed ☐ unsigned Declaration.
☒ A Power of Attorney by Assignee.
☒ A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27 ☒ is enclosed ☐ was filed in the prior application
 and small entity status is still proper and desired.
☒ An Information Disclosure Statement, PTO-1449, and Cited References AA-AG.

	(Col. 1)	(Col. 2)
FOR:	NO. FILED	NO. EXTRA
BASIC FEE		
TOTAL CLAIMS	20 -20=	0
INDEP CLAIMS	4 -3=	1
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RATE	FEE		RATE	FEE
	\$395	OR		\$790
x11=	\$0	OR	x22=	\$
x41=	\$41	OR	x82=	\$
+135=	\$0	OR	+270=	\$
TOTAL	\$436	OR	TOTAL	\$

\$436.00

Respectfully submitted,
 TOWNSEND and TOWNSEND and CREW LLP

James M. Heslin
 Reg. No.: 29,451
 Attorneys for Applicant

PATENT APPLICATION

THERMAL AND HUMIDITY BARRIER FOR EXTREMELY
PREMATURE INFANTS

Inventor:

MARY S. ROGONE, a citizen of the
United States of America, residing at
18090 Harbor Drive
Victorville, California 92392

AUSTIN J. WEBBER II, a citizen of the
United States of America, residing at
2689 Gem Circle
La Verne, California 91750

Assignee:

SMALL BEGINNINGS
Post Office Box 9231-SVL
Victorville, California 92392

Entity:

Small Entity

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
(650) 326-2400

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THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS

BACKGROUND OF THE INVENTION

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1. Field of Invention

This invention relates generally to the treatment of extremely premature infants, and more specifically to an improved thermal barrier and its use for providing a neutral thermal environment.

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2. Description of the Relevant Art

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Maintenance of body temperature in premature infants is of critical importance to their health and survivability. At the present time, there are many infant warmers in use for the treatment and maintenance of babies. Such infant warmers typically include an overhead infrared heater, which is the source of the warmth for an infant placed in the warmer. Such devices usually offer an efficient means for rewarming infants who have been cold stressed, while allowing access to the infant for emergency resuscitation, diagnostic, and therapeutic procedures, and further enabling uninterrupted heat delivery for maintenance of body temperature during routine nursing and medical care.

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While radiant warmers perform adequately in providing for the environmental needs of premature infants (30-36 weeks gestational age) or full-term infants (36 weeks and above gestational age), the needs of the extremely premature neonate are not sufficiently met. An extremely premature neonate, which has a gestational age of between 24 and 28 weeks, and/or a birth weight of less than 1,000 grams (1-2 lbs.), is subject to a degree of cold stress that a less premature or full-term infant does not experience. One of the most challenging aspects in caring for an extremely premature neonate is body temperature maintenance. The extremely

premature neonate has very little ability to maintain its own body temperature. The extremely premature neonate is therefore extremely sensitive to environmental temperature changes. When an extremely premature neonate is subject to a volatile temperature environment, causing a decrease in body temperature, a spiraling course of reactions occur. Body metabolism rates increase in an attempt to raise body temperature. The metabolic increase, in turn, leads to increased oxygen consumption, which can be devastating to an extremely premature neonate who is already in a state of respiratory compromise due to its inherent lung prematurity. Caloric consumption is also increased, which is a critical factor to the well being of an already weight compromised infant (less than 1000 gm). Moreover, it is typical for an extremely premature neonate to have a very underdeveloped skin system. Because of the thin, gelatinous nature of the extremely premature neonate's skin, the neonate is at risk for significant insensible water loss which can effect every body system and can lead to dehydration with significant electrolyte and fluid imbalances and further weight loss.

To prevent these life threatening events from occurring, it is desirable that significant variation in the extremely premature neonate's environment be reduced to the extent possible. A neutral thermal environment with a constant temperature and humidity level is sought so that the extremely premature neonate's body systems are not in a constant struggle to adapt. The environment must occupy a relatively small volume, since even incubator volumes are relatively large and contain variations in temperatures and humidity that are considered too low and too variable. The environment must be maintained even when the patient is undergoing procedures or examination. In the past, various makeshift techniques have been used in an attempt to cover an extremely premature neonate exposed on a warmer bed, including enclosing the warmer bed in plastic wrap. However, the neutral thermal environment is continuously disturbed when frequent access to the patient is required. In the care of an

extremely premature neonate, the acuity level of the neonate requires that the clinician have almost constant access.

In light of the above identified problems with the need to maintain a neutral thermal environment and a consistent humidity level for extremely premature infants, a device is needed that will create a thermal barrier around the patient which creates this consistent neutral environment. Moreover, the device must be designed such that access to the patient is made practical with minimal change to the humidity provided and the neutral thermal environment.

SUMMARY OF THE INVENTION

The present invention provides a moisture and thermal barrier for the maintenance of an improved neutral thermal and humidified environment when used with a specialized heating and humidifying apparatus. The device can surround an extremely premature neonate (less than 1000 gm and 24 to 28 weeks gestational age) to provide an environment with substantially constant temperature and humidity levels. Maintenance of the neutral thermal and humidified environment reduces insensible water loss in the infant and reduces excessive oxygen consumption. The thermal barrier may have covered flexible openings for manual access to the patient for conducting medical procedures. By eliminating the need for removing the barrier for patient access, air exchange and loss of heat, moisture, warmth, and humidity are substantially eliminated during almost the entire course of patient care. Advantageously, the barrier may be made from a clear, medium-weight, plastic-like material, to provide for complete and constant visualization of the patient. Moreover, the thermal barrier is suitable for use with X-ray and other visualization equipment.

In one aspect, a thermal and moisture barrier device for use with a specialized heating and humidifying apparatus in the care of extremely premature neonatal infants is provided. The barrier comprises a collapsible and substantially flexible cover which defines an enclosed volume,

large enough to accommodate an extremely premature neonatal infant. Also provided is at least one flexible opening, located on a portion of the cover which communicates with the enclosed volume. Advantageously, a diaphragm provides closure of the flexible openings. The diaphragm is a resiliently flexible sheet extending across the opening and has slits.

In another aspect of the invention, the thermal and moisture barrier is used in conjunction with an incubator or similar device. The barrier can be a free-standing tetrahedral or right circular cylinder enclosure. An edge portion of the barrier can have an edge portion that creates a seal with a bed or other surface, when the device is placed over an extremely premature infant. A further understanding of the nature and advantages of the present invention may be realized by reference to the remaining portions of the specification and the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a thermal barrier according to the present invention shown above the bed of a radiant warmer prior to being placed in the preferred position;

Fig. 2 is a perspective view of a specific embodiment of the present invention;

Fig. 3 is a perspective view of a right circular cylinder embodiment of the thermal barrier;

Fig. 4 is a perspective view of a tetrahedral embodiment of the thermal barrier;

Fig. 5 is a perspective view of the embodiment of Fig. 4 placed in a typical incubator device.

DESCRIPTION OF A SPECIFIC EMBODIMENT

The present invention provides a thermal and moisture barrier for maintaining an improved neutral thermal and humidified environment. Generally, a barrier is used with open radiant warmer beds or convection warmed infant

incubators to provide a constant environment having consistent temperature and humidity levels. The barrier may be formed from a single sheet of flexible, clear plastic, vinyl, or similar material. In use, the barrier is placed completely over the infant, so that its inner surface is close to but does not contact the infants skin. Thus, the barrier is able to capture a volume of dead air space within the infant's micro-environment.

The thermal and moisture barrier is designed to retain its shape under the warming conditions of infrared lamps or the convective heat of an incubator. The barrier is easily and quickly placed over the infant where it is held in position either under its own weight, with weights added at an edge portion or with a securing means such as, pins, tape, Velcro strips, or any other suitable but temporary adhesive.

The barrier may be made from a flexible, resilient, medium weight material, such as plastic or the like, which can maintain its shape while subjected to warming conditions. Specifically, the material may be a 12 to 15 gauge flexible, clear plastic. While most plastic materials meet the structural requirement standards for the barrier, they are also inexpensive enough to be considered disposable. The inherent rigidity of the plastic is also desirable in that it enables the barrier to be easily cleaned and reused "if necessary." Furthermore, the barrier material can be cut or punctured to enable placement of, for example, respirator tubes, intravenous lines, and the like, without effecting the neutral thermal environment. It may be necessary to incorporate ridges or other structural enhancements to enable the overall barrier to be self-supporting, and not collapse over the infant. Such ridges are easily formed into most plastic materials and methods for forming such ridges are well known.

It has been observed that removal of a thermal barrier can quickly and drastically cause a reduction in the temperature surrounding the infant. Thus, drastically disturbing the neutral thermal environment. To prevent this, flexible, covered openings are provided for manual access of

the patient. This allows immediate access to the infant within the barrier for suctioning, taking vital signs, and the like, while still maintaining the thermal environment surrounding the premature infant. When manual access to the patient is no longer necessary, a plastic covering, made of a resiliently flexible material, is made to overlap the flexible openings which enables the natural self-adhering tendency of the plastic materials to form a seal around the flexible openings.

The thermal and moisture barrier is preferably made from a clear material, so that it is transparent to the infrared lights that warm the infant, as well as being optically transparent for unobstructed and undistorted viewing of the infant. Even though optically clear, however, the barrier's material reduces sound levels within its totally enclosed confines, and thus serves to provide an acoustically sensory-deprived environment. This is felt to be desirable, especially in the active and sometimes loud environment of an intensive care nursery.

Fig. 1 illustrates a thermal and moisture barrier 10 placed over the bed portion B of a radiant warmer R. The barrier is sized and shaped to cover, but not touch, the extremely premature neonate N. The advantage of such an enclosure is that it creates a neutral thermal micro-environment which surrounds an extremely premature neonate. Generally, in one exemplary embodiment, the thermal barrier has a cover 15 and flap portions 42. Typically, flap portions 42 are made to overhang side panels S of radiant warmer bed B. Barrier 10 is designed to be held in place under its own weight, however, weights may be disposed in edge portion 44 to ensure that a constant seal is maintained. Access to the patient is provided through flexible openings 18 disposed on cover 15.

Referring now to Fig. 2 which illustrates a specific embodiment of the present invention. The thermal barrier is a substantially flexible cover 15 which defines an enclosure to accommodate a neonatal infant. The enclosure is created when cover 15 is placed over the bed portion of a radiant warmer.

In the specific embodiment shown, the barrier is formed from a substantially rectangular sheet. The sheet has a flexible seam 40 which is coupled at each of its edges to flap portions 42. Seam 40 acts as a hinge, such that flap portions 42 are pivotally moveable. The seam is created using a heat seal, radiofrequency seal, or any other seal which may be suitable. The sheet may be substantially the same size as the bedding portion of the radiant warmer, such that flap portions 42 overhang side panels of the radiant warmer and create a substantially enclosed environment. The dimensions of the barrier may range from approximately 13 by 24 inches to 25 by 30 inches, depending on the size of the subject radiant warmer.

To ensure that the improved environment is maintained during the conducting of medically necessary procedures, cover 15 has at least one flexible opening 18 located on a portion of the cover. Opening 18 provides communication with the enclosed volume captured by the cover. The opening has a diaphragm 30 which provides closure of flexible opening 18 when it is not in use. Diaphragm 30 is a self-acting closing device, that opens and closes when a clinician's hand or an instrument is urged into the enclosed space. To create the diaphragm, a resiliently flexible material 30 is extended across opening 18 which has a plurality of slits 35. Slits 35 may be configured in any manner that provides the self-acting closing function, however, in a preferred configuration, the slits extend radially outward from the center of the opening and have a common junction point located substantially centrally of flexible opening 18. For added protection of the neutral thermal environment, diaphragm 30 may comprise a superposed sheet of flexible material 20, preferably plastic, for covering the diaphragm. Cover material 20 is secured on to cover 15 at a location proximate to openings 18 and overlaps diaphragm 30, including slits 35 and ensures that no air is either leaking in or out of the enclosed micro-environment. The overlap acts as a simple seal which is formed by taking

advantage of the inherent self-adhesive nature of plastic surfaces.

5 Placement of flexible openings 18 on the surface of the barrier is not critical and may be done in any suitable configuration. The openings can take any conceivable shape and size that allows for adequate access to the patient. The size or shape of the openings can be variable, but the openings should be large enough to accommodate a human hand. The number of openings is preferably 4 so that at least two
10 pairs of hands can have access at the same time. However, the number of openings can vary depending on the special needs of the user or market demand.

Referring now to Figs. 3 and 4 which illustrate perspective views of a right circular cylinder and a
15 tetrahedral exemplary embodiment of the thermal and moisture barrier of the present invention, respectively. In each of the exemplary embodiments, cover 15 is formed into the desired shape using molded clear plastic, or other similar material. The shape can also be manufactured by fashioning seams 38 at
20 edges 44. The seams can be either created, for example, by heat seal, hot glue, or radiofrequency bonding. The barriers, in each example, may be reinforced or made structurally rigid by using structural ridges (not shown) or other strengthening devices and methods. The exemplary embodiments may also have
25 flat end portions 62 which can accommodate an extra opening 18 for accessing the patient, or an extra porthole 50 which provides access for IV lines, oxygen hoses, and monitor cables, and the like.

Fig. 5 illustrates thermal and moisture barrier 10
30 of the present invention as used in an incubator I or similar device. The incubator cannot properly maintain a neutral thermal and humidified micro-environment for the extremely premature neonate because of its relatively large volume. Thermal barrier 10 captures a smaller volume of air within the
35 incubator to provide this environment. Flexible openings 18, for access to the patient, can themselves be accessed through portholes P, typically found on incubator devices.

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WHAT IS CLAIMED IS:

1 1. A thermal and moisture barrier for use with a
2 specialized heating and humidifying apparatus having a bed
3 portion used in the care of a neonatal infant comprising;
4 a substantially flexible cover defining when placed
5 over the bed an enclosure to accommodate a neonatal infant;
6 and
7 at least one opening located through the cover and
8 permitting manual access into the enclosure.

1 2. The barrier of claim 1, wherein the at least
2 one opening has a diaphragm providing a manually penetrable
3 closure.

1 3. The barrier of claim 2, wherein the diaphragm
2 comprises a resiliently flexible material extending across the
3 opening and having slits therein.

1 4. The barrier of claim 3, wherein the slits
2 extend radially outward having a common junction point located
3 substantially centrally of the flexible opening.

1 5. The barrier of claim 1, further comprising a
2 layer of flexible material positioned proximate to the opening
3 which overlaps the opening to form a seal.

1 6. The barrier of claim 1, wherein the cover is
2 formed from a substantially rectangular sheet, the sheet being
3 pivotally coupled by a flexible seam at each of its edges to
4 flap portions, the sheet being substantially the same size as
5 an open bedding portion of a radiant warmer such that the flap
6 portions overhang side panels of the radiant warmer and create
7 a substantially enclosed environment.

1 7. The barrier of claim 1, wherein the cover
2 defines a tetrahedral enclosure, the cover further comprising
3 an edge portion that creates a seal.

1 8. The barrier of claim 1, wherein the cover
2 defines a half section of a truncated right circular cylinder
3 enclosure, the cover further comprising an edge portion that
4 creates a seal.

1 9. The barrier of claim 1, wherein the cover
2 comprises an optically transparent material.

1 10. In an infant radiant warmer comprising a
2 bassinet assembly and a plurality of optically transparent
3 side panels surrounding a mattress upon which an infant can be
4 placed, the improvement comprising:

5 a substantially flexible cover defining an enclosure
6 when disposed over the mattress to accommodate a neonatal
7 infant; and

8 at least one opening located through the cover and
9 permitting manual access into the enclosure.

1 11. The improved radiant warmer of claim 10, having
2 a diaphragm providing a manually penetrable closure of the at
3 least one flexible opening.

1 12. The improved radiant warmer of claim 11,
2 wherein the diaphragm comprises a resiliently flexible sheet
3 extending across the opening and having slits extending
4 radially outward having a common junction point located
5 substantially centrally of the flexible opening.

1 13. The improved radiant warmer of claim 11,
2 wherein the diaphragm comprises a superposed sheet of flexible
3 material for covering the diaphragm when not in use.

1 14. The improved radiant warmer of claim 10,
2 wherein the cover defines a substantially rectangular sheet,
3 the sheet having a flexible seam at each of its edges coupled
4 to flap portions, wherein the flap portions overhang the side
5 panels and create a substantially enclosed environment.

1 15. The improved radiant warmer of claim 10,
2 wherein the cover defines a section of a portion of a right
3 circular cylinder enclosure, the cover further comprising an
4 edge portion that creates a seal with the mattress.

1 16. The improved radiant warmer of claim 10,
2 wherein the cover defines a tetrahedral enclosure, the cover
3 further comprising an edge portion that creates a seal with
4 the mattress.

1 17. In an incubator comprising an incubation
2 chamber, optically transparent side walls having armholes
3 therein, surrounding a mattress upon which an infant can be
4 placed, the improvement comprising:

5 a substantially flexible cover defining an enclosure
6 when disposed over the mattress to accommodate a neonatal
7 infant, wherein the cover comprises an edge portion that
8 creates a seal with the mattress providing a neutral thermal
9 environment therein; and

10 a plurality of flexible openings located on a
11 portion of the cover and communicating with the enclosure,
12 wherein the openings have a diaphragm comprising a resiliently
13 flexible sheet extending across the opening and having slits
14 extending radially outward having a common junction point
15 located substantially centrally of the flexible opening which
16 provide closure to preserve the neutral thermal and humidified
17 environment.

1 18. A method for providing a thermal and moisture
2 barrier for use with a specialized heating and humidifying
3 apparatus having a bed portion used in the care of a neonatal
4 infant comprising the steps of:

5 covering the infant with a substantially flexible
6 cover which defines an enclosure when placed over the bed
7 portion; and

8 permitting manual access into the enclosure through
9 at least one opening located through the cover.

20. The method of claim 18, wherein the cover is formed from a substantially rectangular sheet, the sheet being pivotally coupled by a flexible seam at each of its edges to flap portions, the sheet being substantially the same size as an open bedding portion of a radiant warmer such that the flap portions overhang side panels of the radiant warmer and create a substantially enclosed environment.

THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS

ABSTRACT OF THE DISCLOSURE

5 A thermal and moisture barrier device for use with a
specialized heating and humidifying apparatus in the care of
extremely premature neonatal infants. The thermal and
moisture barrier comprises a collapsible and substantially
10 flexible cover which defines an enclosed volume, large enough
to accommodate an extremely premature neonatal infant. At
least one flexible opening is located on a portion of the
cover which communicates with the enclosed volume. A
diaphragm provides closure of the flexible openings. The
15 diaphragm is a resiliently flexible sheet extending across the
opening and has slits.

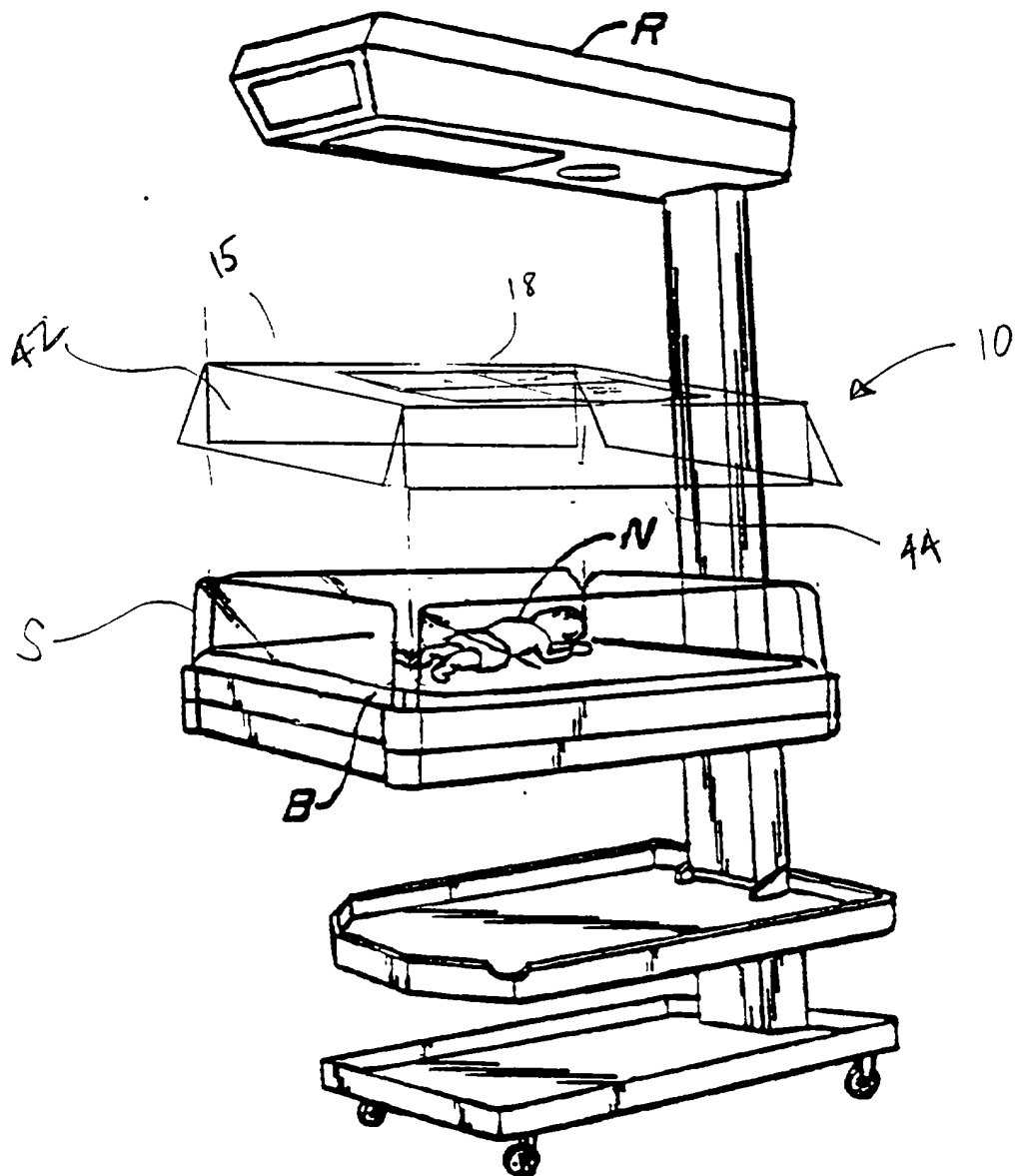


FIG. 1.

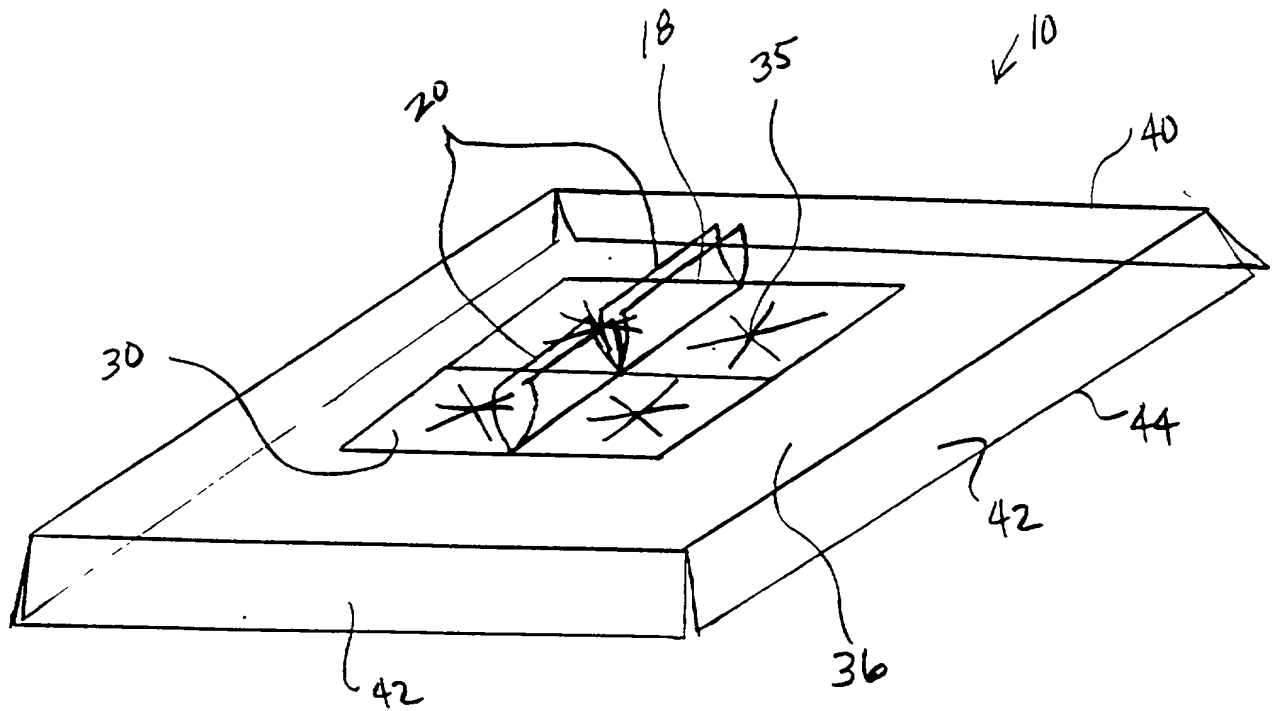
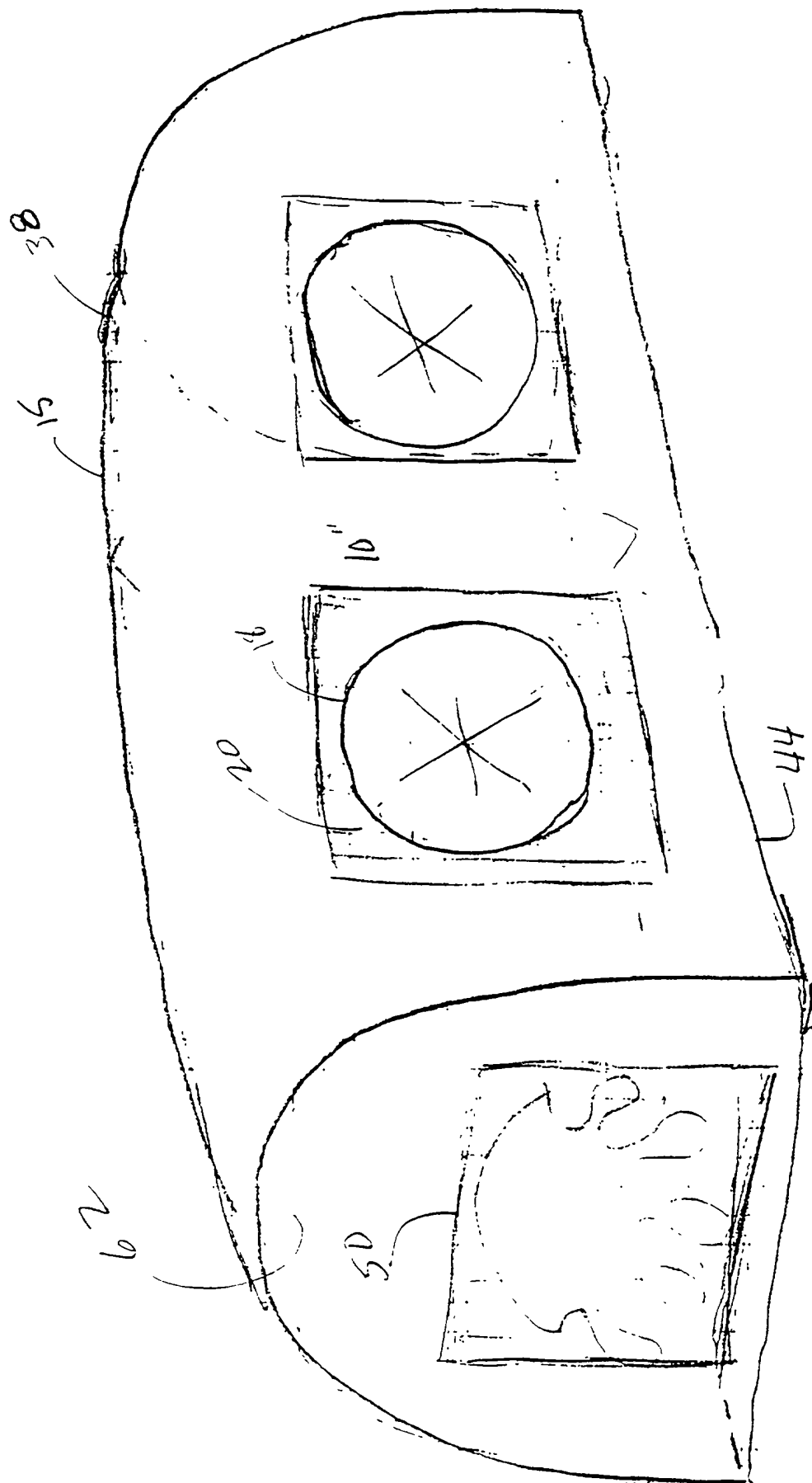


FIG. 2

[illegible]

2.1.1

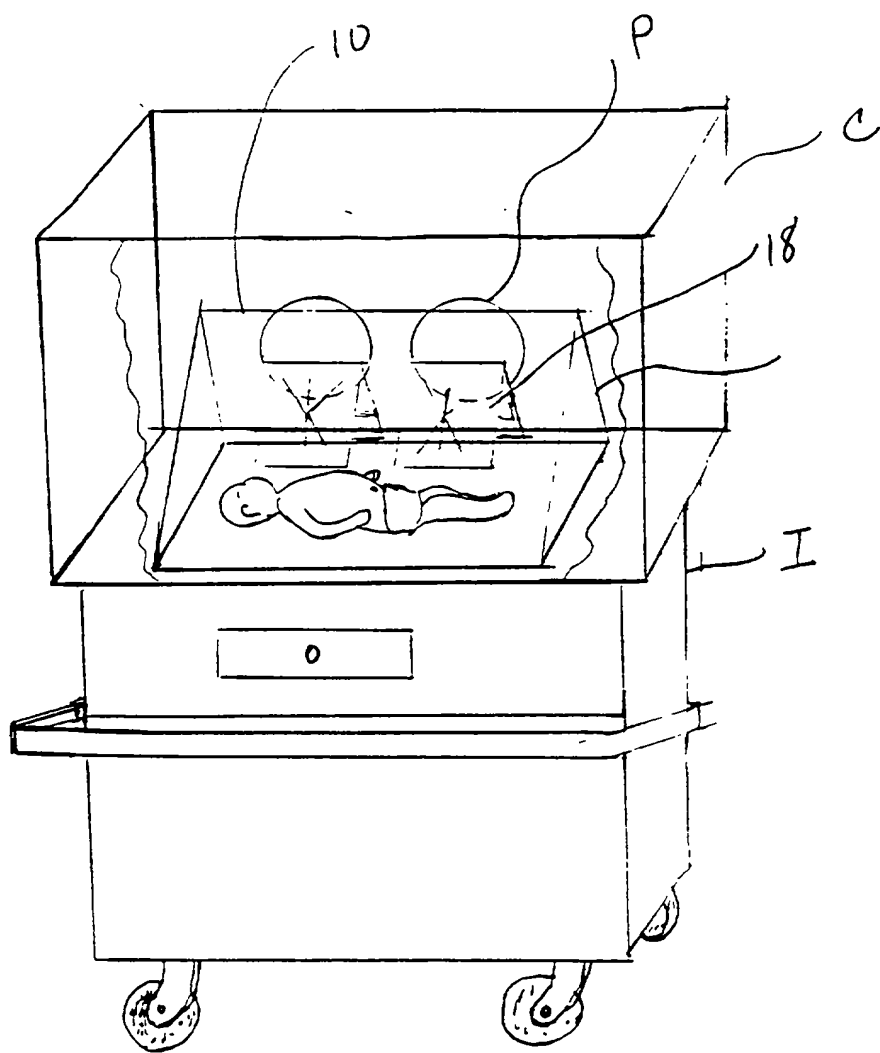


FIG. 5

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS** the specification of which X is attached hereto or ___ was filed on ___ as Application No. ___ and was amended on ___ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign applications(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119
			Yes _ No _
			Yes _ No _

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

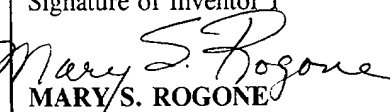
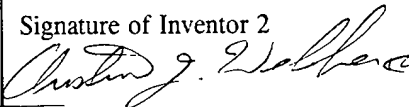
Application No.	Filing Date

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status
		_ Patented _ Pending _ Abandoned
		_ Patented _ Pending _ Abandoned

Full Name of Inventor 1	Last Name ROGONE	First Name MARY	Middle Name or Initial S.	
Residence & Citizenship	City Victorville	State/Foreign Country California	Country of Citizenship United States	
Post Office Address	Post Office Address 18090 Harbor Drive	City Victorville	State/Country California	Zip Code 92392
Full Name of Inventor 2	Last Name WEBBER II	First Name AUSTIN	Middle Name or Initial J.	
Residence & Citizenship	City La Verne	State/Foreign Country California	Country of Citizenship United States	
Post Office Address	Post Office Address 2689 Gem Circle	City La Verne	State/Country California	Zip Code 91750
Full Name of Inventor 3	Last Name	First Name	Middle Name or Initial	
Residence & Citizenship	City	State/Foreign Country	Country of Citizenship	
Post Office Address	Post Office Address	City	State/Country	Zip Code

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1  MARY S. ROGONE	Signature of Inventor 2  AUSTIN J. WEBBER II	Signature of Inventor 3
Date 3/29/98	Date 3/29/98	Date

POWER OF ATTORNEY BY ASSIGNEE

SMALL BEGINNINGS, Post Office Box 9231-SVL, Victorville, California 92392,
is the Assignee of the invention entitled:

THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS

The specification of which X is attached hereto or was filed on as Application No. .

The Assignment accompanying this Power of Attorney has been reviewed by the undersigned. The undersigned certifies that to the best of the undersigned's knowledge and belief, title is in the Assignee. The undersigned (whose title is supplied below) is empowered to act on behalf of the Assignee.

Assignee hereby appoints the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

James M. Heslin, Reg. No. 29,541	Darin J. Gibby, Reg. No. 38,464
Gary T. Aka, Reg. No. 29,038	Mark D. Barrish, Reg. No. 36,443
Robert C. Colwell, Reg. No. 27,431	Joe Liebeschuetz, Reg. No. 37,505
Paul C. Haughey, Reg. No. 31,836	James F. Hann, Reg. No. 29,719
David N. Slone, Reg. No. 28,572	Randolph T. Apple, Reg. No. 36,429
William M. Smith, Reg. No. 30,223	John R. Storella, Reg. No. 32,944
Renee A. Fitts, Reg. No. 35,136	Margaret A. Powers, Reg. No. 39,804
Lorie A. Morgan, Reg. No. 38,181	Hao Y. Tung, Reg. No. P43,209

Send Correspondence to:
James M. Heslin, Esq.
TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111-3834

Direct Telephone Calls to:

James M. Heslin, Esq.
Reg. No. 29,541
650/326-2400

SMALL BEGINNINGS

Date: 3/29/98

By:

Mary S. Rogone
MARY S. ROGONE

Title:

Director

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN

Applicant or Patentee: MARY S. ROGONE and AUSTIN J. WEBBER IIApplication or Patent No.: UnassignedFiled or Issued: HerewithTitle: THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Small Business Concern: SMALL BEGINNINGSAddress of Small Business Concern: Post Office Box 9231-SVL
Victorville, California 92392

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled THERMAL AND HUMIDITY BARRIER FOR EXTREMELY PREMATURE INFANTS by inventor(s) Mary S. Rogone and Austin J. Webber II described in:

- ☒ the specification filed herewith.
☐ Application No. _____, filed _____.
☐ Patent No. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

Name _____
 Address _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Name _____
 Address _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Mary S. Rogone
 Title of Person if Other than Owner: Director
 Address of Person Signing: Post Office Box 9231-SVL
Victorville, California 92392

Signature Mary S. Rogone
 MARY S. ROGONE

Date 2-29-98